

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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Memorandum:

12/8/87

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 100-577. Diazinon Data Call-In. Comments On Protocol
For Storage Stability Studies Of Fortified Crop
Matrices. (RCB #2908, no MRID or Acc #'s)

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THRU: Philip V. Errico, Section Head III
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TO: George LaRocca, PM-15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

In response to the Agency's Data Call-In dated May 1, 1987 for the Diazinon Registration Standard, CIBA-GEIGY has submitted a cover letter dated August 7, 1987 (See letter of C.B. Bussey, CIBA-GEIGY Regulatory Specialist, Diazinon Reg. Std. file) and a protocol for a storage stability studies of diazinon-fortified crop samples.

In Summary:

1. The protocol is acceptable and should provide adequate data, except that a tomato or apple crop matrix should be added to the proposed study; also leafy lettuce should be used.

2. RCB has no objection to an 18-month extension of the due date from 11/88 to 5/90, however, extensions are administrative decisions made in the Registration Division. The minimum time necessary to carryout this storage stability study is 15 months since samples must be stored for 12 months. Additional time will be required if field treated samples are stored longer than 12 months.

3. RCB will accept storage stability studies with fortified samples OR field-weathered crop samples rather than with both.

4. The registrant will not provide residue data to support the established tolerances for grass forage and non-grass commodities. If uses will not be supported by other interested parties, then these tolerances should be revoked.

Diazinon Registration Standard Requirements:

"To support crop residue data, storage stability studies must be conducted on both weathered samples and fortified frozen samples of one representative crop from each crop grouping (§40 CRF 180.34) on which registered uses of diazinon exist.

Data are required on diazinon and metabolites of concern in which a group of untreated samples of raw agricultural commodities and processed crops are fortified (spiked) with only diazinon (pure active ingredient) and other groups are fortified individually with each metabolite of concern."

CIBA-GEIGY's Response:

A study protocol has been submitted by the registrant. (See Diazinon Reg. Std. file, CIBA-GEIGY project number: 302925) In summary, the registrant has proposed to use four crop matrices, i.e., potatoes, dry beans, corn, and lettuce, and to use processed products, i.e., apple juice, dry tomato pomace, sugar beet pulp, citrus oil, sugar beet molasses, soybean meal, raisins, potato granules, and catsup. Samples will be fortified with 0.50 ppm diazinon and metabolites and then analyzed at day zero, and 3, 6, 9, and 12 months. Analytical methods will be developed once the metabolites are determined based upon the plant metabolic studies. The proposed completion date is 5/90; thus an extension of 18 months is requested (EPA due date 11/88).

RCB Comments/Conclusions:

The protocol is acceptable and should provide adequate data for root and tuber vegetables, legume, cereal grains, and leafy vegetables. A fruiting vegetable (tomato) or a pome fruit (apple) raw agricultural commodity should be added to the proposed study. Also leafy lettuce should be used instead of head lettuce. Catsup should be replaced with tomato puree. These crops should give an adequate variety of crop matrices which will satisfy RCB's requirements for storage stability data for diazinon. RCB will accept storage stability studies with fortified samples OR field-weathered crop samples rather than with both; the perferred choice is field-weathered residues. The registrant should conduct the storage stability study so it reflects the storage conditions of the samples used to support their residue field trial results; if the residue field trial samples were stored for greater than

12 months, then samples at longer storage times should be included, e.g., instead of 0, 3, 6, and 12 months, use 0, 3, 12, and 24 months to reflect samples stored up to 24 months. RCB has no objection to an 18-month extension for fortified samples; the new due date would be 5/90.

Note to PM: The registrant will not provide residue data to support the established tolerances for grass forage and non-grass commodities (See forementioned cover letter dated 8/7/87). Adequate data to support these uses must be available to the Agency. If uses will not be supported by other interested parties, then these tolerances should be revoked.

cc: R.F.; PMSD/ISB; PM-15; J. Stokes; S.F.; Diazinon Reg. Std.;
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RDI: Perrico:12/7/87:RSchmitt:12/7/87

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